

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

**Proposing rule making related to Iowa care for yourself program
and providing an opportunity for public comment**

The Public Health Department hereby proposes to amend Chapter 8, “Iowa Care for Yourself (IA CFY) Program,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 135.11(1).

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 135.11(1).

Purpose and Summary

The proposed amendments update Chapter 8 to reflect the current practices of the IA CFY Program.

Recognizing the value of screening and early detection of breast and cervical cancer, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 and in 1993 authorized additional preventative health services to participants in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The Breast and Cervical Cancer Early Detection Program (BCCEDP) provides screening for breast and cervical cancer.

In addition, the Well-Integrated Screening and Evaluation for Women Across the Nation Program (WISEWOMAN) provides preventative screening for cardiovascular disease risk factors. Cardiovascular-related lifestyle interventions, tailored to each individual’s cardiovascular screening results and the individual’s readiness to make lifestyle behavior changes, are also offered to participants. These two programs are funded through cooperative agreements with the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). Iowa first received CDC funding in 1993 for the BCCEDP and began providing early detection services in 1995. Iowa received funding for WISEWOMAN as a research study in 2001 and started providing limited services in 2003. The current framework of services as a standard program was implemented in 2018.

The rules in Chapter 8 allow the services offered through the BCCEDP and WISEWOMAN to be offered in Iowa under one program, the IA CFY Program. The purposes of the IA CFY Program are to provide breast and cervical cancer screening and diagnostic services and cardiovascular risk factor screening and intervention services to low-income, uninsured, underinsured and underserved women, to provide public and professional development, and to support community partnerships enhancing statewide breast and cervical cancer and cardiovascular disease control activities. Chapter 8 covers agencies designated by contracting county boards of health to provide community-based IA CFY Program services and to receive funds from the Department for that purpose. The designated agencies facilitate the essential screening and diagnostic services consistent with CDC and IA CFY Program guidelines.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department's waiver and variance provisions contained in 641—Chapter 178.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on December 10, 2019. Comments should be directed to:

Jill Myers-Geadelmann
Department of Public Health
Lucas State Office Building
321 East 12th Street
Des Moines, Iowa 50319
Email: jill.myers-geadelmann@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)“b,” an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Amend **641—Chapter 8** as follows:

CHAPTER 8 IOWA CARE FOR YOURSELF (IA CFY) PROGRAM [Prior to 4/4/12, see 641—Chapter 37]

641—8.1(135) Definitions. For purposes of this chapter, the following definitions apply:

“*Abnormal screen*” means a suspicion of breast or cervical cancer or laboratory values of total cholesterol or blood glucose and average blood pressure reading in the range defined by the CDC according to National Heart, Lung and Blood Institute guidelines.

1. A suspicion of breast cancer includes clinical breast examination findings of: palpable breast mass, breast dimpling, nipple retraction, bloody nipple discharge, palpable lymph nodes around clavicle or axilla, nipple erythema and scaliness, a mammography result of breast imaging reporting and data systems (BI-RADS) category 4 (suspicious abnormality suggesting need for biopsy) or category 5 (highly suggestive of malignancy) (ICD-9-793.8 ~~10~~ R92.0, R92.1, R92.2, R92.8), breast biopsy result of ductal cancer in situ (ICD-10 D05.10, D05.11, D05.12), lobular cancer in situ (ICD-9-233.0 ~~10~~ D05.00, D05.01, D05.02), or breast or lymph node (or other) biopsy result of breast cancer.

2. Suspicion of cervical cancer is a Pap test result of atypical squamous cells cannot exclude high-grade squamous intraepithelial lesions (ASC-H) (ICD-9-795.02 ~~10~~ R87.611 or R87.622), atypical glandular cells (AGC) (ICD-9-795.00 ~~10~~ R87.619 or R87.629), low-grade squamous intraepithelial

lesions (LSIL) (ICD-9 ~~622.11 or 795.03~~ 10 R87.612 or R87.622), or high-grade squamous intraepithelial lesions (HSIL) (ICD-9 ~~622.12 or 795.04~~ 10 R87.613 or R87.623), leukoplakia of the cervix (ICD-9 ~~622.2~~ 10 N88.0), or cervical biopsy result of cervical intraepithelial neoplasia II (ICD-10 N.87.1) or III (ICD-9 ~~622.10, 622.11, 622.12, 795.03, or 795.04~~ 10 D06.0, D06.1, D06.7 or D06.9), or cancer in situ (ICD-9 ~~233.1~~ 10 D06.0, D06.1, D06.7 or D06.9).

3. Abnormal value means laboratory values of total cholesterol or blood glucose (HbA1c if diagnosed diabetic) and average blood pressure reading in the range defined by the CDC according to National Heart, Lung and Blood Institute guidelines.

“ACR” or “American College of Radiology” means one of the Food and Drug Administration-recognized accreditation bodies for minimum quality standards for personnel, equipment, and record keeping in facilities that provide ~~mammography~~ breast imaging.

“Advanced registered nurse practitioner” means an individual licensed to practice under 655—Chapter 7.

“Alert value” means laboratory values of total cholesterol, ~~or~~ blood glucose ~~and or~~ average blood pressure reading in the range defined by the CDC according to National Heart, Lung and Blood Institute guidelines.

“BCCPTA” or “Breast and Cervical Cancer Prevention and Treatment Act of 2000” means a federal law that provides each state with the option of extending Medicaid eligibility to ~~women~~ individuals who were diagnosed with breast or cervical cancer through the National Breast and Cervical Cancer Early Detection Program.

“BCCT option of Medicaid” or “breast and cervical cancer treatment option of Medicaid” means the optional program of medical aid designed for ~~women~~ individuals who are unable to afford regular medical service and are diagnosed with breast or cervical precancer or cancer through the National Breast and Cervical Cancer Early Detection Program or through funds from Susan G. Komen for the Cure family planning centers, community health centers, or nonprofit organizations. The individuals who receive screening or services meet eligibility requirements established by the Iowa care for yourself program. The BCCT option of Medicaid is financed by federal and state payment sources and is authorized by Title XIX of the Social Security Act.

“Benign” means a noncancerous condition that does not spread to other parts of the body.

“Biopsy” means the removal of a sample or an entire abnormality for microscopic examination to diagnose a problem. Examples of a sampling would be a core biopsy or incisional biopsy; an example of entire removal would be an excisional biopsy.

“BI-RADS” or “breast imaging reporting and data systems” means a standardized reporting system for mammography, breast ultrasound and breast magnetic resonance imaging (MRI) reports.

“Blood glucose” means a simple sugar found in the blood that is an important energy source in living organisms and is a component of many carbohydrates.

“Blood pressure” means the ~~pressure or tension~~ force of the blood within against the systemic arteries, maintained by the contraction of the left ventricle, the resistance of the arterioles and capillaries, the elasticity of the arterial walls, as well as the viscosity and volume of the blood; expressed as relative to the ambient atmospheric pressure circulatory system. The systolic blood pressure is the force caused when the heart contracts and pushes out the blood. The diastolic blood pressure is when the heart relaxes and fills with blood.

“BMI” or “body-mass index” means ~~a number calculated from a person’s weight and height~~ an index for relating weight to height. BMI provides a reliable indicator of body fatness for most people and is used to screen for weight categories that may lead to health problems.

“Breast ultrasound” means ~~the use of an imaging technique commonly used to screen for tumors and other breast abnormalities. The breast ultrasound uses high-energy sound waves that are bounced off internal tissues and make echoes to produce a pictorial representation of the internal structure~~ detailed image of the inside of the breast.

“Cancer” means ~~a malignant tumor of potentially unlimited growth of new cells that expand locally by invasion and systemically by metastasis~~ group of diseases involving abnormal cell growth with the potential to invade or spread to other parts of the body.

“Carcinoma in situ” means cell changes in which malignant cells are localized and may press against adjoining tissue but have not penetrated or spread beyond their site of origin a group of abnormal cells found only in the place where they first formed in the body.

“Cardiologist” means a physician licensed to practice under Iowa Code chapter 148 who specializes in the study of the heart and its action and diseases.

“Cardiovascular disease” means a broad term used to describe a range of diseases that affect the heart and, in some cases, blood vessels.

“Cardiovascular disease risk factors” means identifiable factors that make some people more susceptible than others to cardiovascular disease. Cardiovascular disease risk factors include:

1. Obesity.
2. Physical inactivity.
3. High blood pressure.
4. High blood cholesterol.
5. Diabetes.
6. Tobacco use.

Risk factors that cannot be changed are age, gender and family history. The more cardiovascular disease risk factors a person has increases the person’s chance of developing cardiovascular disease.

“Case management” means the IA CFY program component that involves establishing, brokering, and sustaining a system of available clinical and essential support services for all ~~women~~ individuals enrolled in the program.

“CBE” or “clinical breast examination” means complete examination of a woman’s an individual’s breast and axilla with palpation by a health care provider, including examination of the breast in both the upright and supine positions trained to recognize many different types of abnormalities and warning signs.

“CDC” means the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services, a federal agency that conducts and supports health promotion, prevention and preparedness activities in the U.S., with the goal of improving overall public health.

“Cholesterol” means a waxy, fat-like substance made in the liver and other cells and found in certain foods, such as foods from animals, for example, dairy products, eggs and meat. Types of cholesterol are as follows:

1. Low density lipoprotein or LDL, also called “bad” cholesterol. LDL can cause buildup of plaque on the walls of arteries. The more LDL there is in the blood, the greater the risk of heart cardiovascular disease.
2. High density lipoprotein or HDL, also called “good” cholesterol. HDL helps the body get rid of bad cholesterol in the blood. If levels of HDL are low, risk of heart cardiovascular disease increases.
3. Very low density lipoprotein or VLDL. VLDL is similar to LDL cholesterol in that it contains mostly fat and not much protein.
4. Total cholesterol means the sum of the very low, low and high density lipoproteins.

“CLIA” or “Clinical Laboratory Improvement Act Acts of 1988” means the law which established federal regulatory standards that apply to all clinical laboratory testing performed on humans in the U.S. These standards establish minimum quality standards for personnel and quality assurance methods that monitor patient test management and assess quality control, proficiency testing, and personnel handling of laboratory and pathology specimens.

“CLIA-waived tests” means simple laboratory examinations and procedures that are cleared by the federal government for home use, that employ methodologies that are so simple and accurate that erroneous results would be negligible, or that pose no reasonable risk of harm to the patient if the test is performed incorrectly.

“CMS” or “Centers for Medicare and Medicaid Services” is a federal agency within the United States Department of Health and Human Services that administers health care programs, including Medicare, Medicaid, the children’s health insurance program (CHIP) and health insurance exchanges, in partnership with state governments.

“Colposcopy” means a medical procedure that allows close examination of the surface of the cervix with a high-powered microscope.

“Community referral” means the act, action or instance of directing a participant to a community resource to direct individuals elsewhere to obtain needed information, mutual support or community resources through help lines or other methods.

“Community resource” means a source of information, service or expertise that is available within the community, including respite care services, health and mental health services and other social services.

“Cooperative agreement” means a signed contract between the department and another party, for example, a health care provider. This contract facility, which allows the department to pay the health care provider facility for providing services to IA CFY program participants.

“CPT” or “current procedural terminology” is a listing of descriptive terms and identifying codes for uniform language to report medical services and procedures performed by qualified health care professionals and allows clinicians, statisticians, politicians, health insurance programs, health planners and others to speak a common language.

“Creditable coverage” means any insurance that pays for medical bills incurred for the screening, diagnosis, or treatment of breast and cervical cancer. Creditable coverage as described by the Health Insurance Portability and Accountability Act of 1996 includes, but is not limited to, group health plans or health insurance coverage consisting of medical care under any hospital or medical service policy, health maintenance organization, Medicare Part A or B, Medicaid, armed forces insurance, or state health risk pool. A woman An individual who has creditable coverage shall not be eligible for coverage under the breast and cervical cancer treatment option of Medicaid.

“Creditable coverage circumstances” means those instances in which a woman an individual has creditable coverage but is not actually covered for treatment of breast or cervical cancer.

1. When there is a preexisting-condition exclusion or when the annual or lifetime limit on benefits has been exhausted, ~~a woman~~ an individual is not considered to have creditable coverage for this treatment.

2. If ~~the woman~~ an individual has limited coverage, such as a high deductible, limited drug coverage, or a limited number of outpatient visits, ~~she~~ the individual is still considered to have creditable coverage and is not eligible for coverage under the breast and cervical cancer treatment option of Medicaid.

3. If ~~the woman~~ an individual has a policy with a limited scope of coverage, such as only dental, vision, or long-term care, or has a policy that covers only a specific disease or illness, ~~she~~ the individual is not considered to have creditable coverage unless the policy provides coverage for breast and cervical cancer treatment.

4. For the purposes of this program, eligibility for Indian Health Services or tribal health care is not considered creditable coverage (according to P.L. 107-121, the Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001).

“Cytology” means the scientific study of cells branch of biology that studies the structure and function of a cell.

“Cytopathology” means the scientific study of cells in disease branch of pathology that studies and diagnoses disease on the cellular level.

“Cytotechnologist” means a medical technician trained in the identification of cells and cellular a laboratory professional who studies cells and cellular abnormalities.

“Department” means the Iowa department of public health.

“DHS” or “department of human services” means the Iowa department of human services, a state agency that provides a wide range of services, including health care coverage for low-income uninsured individuals diagnosed with breast or cervical cancer or precancer and requiring treatment.

“Diagnostic mammography” means a radiological examination performed for appropriate clinical indications, such as breast mass(es), other breast signs or symptoms (spontaneous nipple discharge, skin changes), or special cases, such as a history of breast cancer with breast conservation or augmented breasts.

“Family planning clinic” means a Title X family planning program site dedicated to the provision of family planning and related preventive health services to low-income and underserved populations.

“FDA” or “Food and Drug Administration” means the federal governmental body which certifies that a ~~mammography~~ breast imaging facility meets minimum quality standards for personnel, equipment, and record keeping.

“Follow-up” means the IA CFY program component that involves a system for seeking information about or reviewing an abnormal condition, rescreening, or recall for annual visits.

“Glucose” means a simple sugar that is an important carbohydrate in biology. Cells use glucose as a source of energy and a metabolic intermediate.

“Gynecologist” means a physician licensed to practice under Iowa Code chapter 148 who specializes in diseases of the reproductive organs in women.

“HbA1c” or “glycosylated hemoglobin” means a clinical laboratory test for the purposes of ~~monitoring blood glucose control of a participant diagnosed with diabetes~~ diagnosing diabetes or determining control of diabetes over the past two to three months.

“Health care provider” means any physician, pharmacist, advanced registered nurse practitioner, or physician assistant who is licensed authorized to practice by the state of Iowa; who is performing within the scope of the practice as defined by state law; and who provides care to IA CFY program-enrolled women individuals.

“Heart disease” means a broad term used to describe a range of diseases that affect the heart and, in some cases, blood vessels. The term is often used interchangeably with “cardiovascular disease,” which generally refers to conditions that involve narrowed or blocked blood vessels that can lead to a heart attack, chest pain (angina) or stroke.

“Heart disease risk factors” means identifiable factors that make some people more susceptible than others to heart disease. Heart disease risk factors include:

1. Being overweight.
2. Lack of physical activity.
3. High blood pressure.
4. High blood cholesterol.
5. Diabetes.
6. Cigarette smoking.

Risk factors that cannot be changed are age and family history. The more heart disease risk factors a person has increases the person’s chance of developing heart disease.

“IA BCCEDP” or “Iowa breast and cervical cancer early detection program” means a comprehensive breast and cervical cancer screening program established and funded under Title XV of the federal Public Health Service Act and administered by the Iowa department of public health, with the delegated responsibility of implementation and evaluation from the CDC, Division of Cancer Prevention and Control.

“IA CFY program” or “Iowa care for yourself program” means an integrated comprehensive breast and cervical cancer screening program and cardiovascular risk factor screening and intervention program administered by the Iowa department of public health.

“IA WISEWOMAN” or “Iowa well-integrated screening and evaluation for women across the nation” means a cardiovascular-related risk factor screening and intervention program to provide standard preventive screening services, including blood pressure measurements, cholesterol testing, blood glucose testing, and lifestyle interventions that target poor nutrition, physical inactivity, and tobacco use. The program is authorized by the federal government and administered by the CDC to help reduce deaths and disability from heart cardiovascular disease and stroke.

“ICD-9 ICD-10” or “International Classification of Disease, 9th 10th edition” means a standardized classification of diseases, injuries, and reasons of death, by cause and anatomic localization, which is systematically put into a number of up to six seven digits and which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both in the United States and internationally.

“Infrastructure” means the basic framework of sufficient staff and adequate support systems to plan, implement, and evaluate the components of the IA CFY program.

“In need of treatment” means that a medical or surgical intervention is required because of an abnormal finding of breast or cervical cancer or precancer that was determined as a result of a screening or diagnostic procedure for breast or cervical cancer/precancer ~~under the NBCCEDP.~~

“Intervention” means services that promote a ~~heart-healthy~~ cardiovascular-healthy diet and physical activity and that are based on screening results, which include blood pressure, cholesterol, blood glucose, weight, height, personal medical history, family medical history, and health behavior and readiness-to-change assessments.

“MATE MAB” or *“medical advisory task force board”* means ~~an advisory board~~ a body that may be utilized by the IA CFY program to offer knowledge and experience as related to the fields of expertise of the members of the ~~task force board.~~ Duties of the MATE MAB may include, but are not limited to, the following:

1. Reviewing and making recommendations for clinical service expansion.
2. Reviewing program-developed clinical protocols.
3. Providing recommendations related to other clinical and participant-related issues.
4. Providing input related to quality assurance issues.
5. Reviewing program screening and diagnostic data.

“MDEs” or *“minimum data elements”* means a set of standardized data elements used to collect ~~demographic and clinical information on women whose screening or diagnosis was paid for with IA CFY program funds. MDEs were developed by the CDC, Division of Cancer Prevention and Control, to ensure that consistent and complete information is collected on women whose screening or diagnosis was paid for with IA CFY program funding~~ patient-level screening records on individuals served through the NBCCEDP in order to evaluate whether programs are meeting clinical standards and programmatic priorities.

“Medicaid” means a health care program that assists low-income families or individuals in paying for doctor visits, hospital stays, long-term medical care, custodial care costs and more; the program of ~~medical aid designed for those unable to afford regular medical service,~~ is financed by federal and state payment sources; and authorized by Title XIX of the Social Security Act and administered by the Iowa department of human services.

“Medicare” means the program of federal payment source for health benefits, especially for the aged, which is authorized by Title XVIII of the Social Security Act.

“NBCCEDP” or *“National Breast and Cervical Cancer Early Detection Program”* means a program established with the passage of the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354). The law authorizes the CDC to establish a program of grants to states, tribes, and territories for ~~the purpose of~~ increasing the early detection of breast and cervical cancer, particularly among low-income, uninsured, and underserved ~~women~~ individuals.

“Nonprofit organization” means a group organized for purposes other than generating profit and in which no part of the organization’s income is distributed to its members, directors, or officers, except under limited circumstances.

“Oncologist” means a physician licensed to practice under Iowa Code chapter 148 who is a specialist in treating or studying the physical, chemical, and biologic properties and features of neoplasms, including causation, pathogenesis, and treatment.

“Outreach” means the IA CFY program component that involves recruiting targeted populations or ~~women~~ individuals who never or rarely utilize preventive health services.

“Pap test” means the Papanicolaou screening test that collects cells from the cervix for examination under a microscope. The Pap test can detect abnormal cells or precancerous cells before cancer develops.

“Pathologist” means a physician licensed to practice under Iowa Code chapter 148 who is a specialist in identifying diseases by studying cells and tissues under a microscope.

“Patient navigation” means an IA CFY program component that assists individuals in overcoming health care system barriers and facilitates timely access to quality screening and diagnostics as well as initiation of breast or cervical cancer treatment services.

“Pharmacist” means an individual licensed to practice under Iowa Code chapter 155A.

“Physician” means an individual licensed to practice under Iowa Code chapter 148.

“Physician assistant” means an individual licensed to practice under Iowa Code chapter 148C.

“Precancerous” means a condition that may become, or is likely to become, or lesion involving abnormal cells that are associated with an increased risk of developing into cancer.

“Program and fiscal management” means the IA CFY program component that includes planning, organizing, directing, coordinating, managing, budgeting for, and evaluating program activities.

“Quitline Iowa” means a toll-free, statewide smoking cessation telephone counseling hotline through which trained counselors provide earlier assistance in making an individualized tobacco use quit plan and provide ongoing support through optional follow-up calls.

“Radiologist” means a physician licensed to practice under Iowa Code chapter 148 who specializes in creating and interpreting pictures of areas inside the body. The pictures are produced with the branch of medicine that diagnoses injuries and diseases using medical imaging procedures such as X-rays, sound waves, or other types of energy.

“Rarely or never been screened” means, as defined for the NBCCEDP, that a woman an individual has not had cervical cancer screening within the last five years or has never been screened for cervical cancer.

“Recruitment” means the IA CFY program component that involves enrolling targeted populations or women individuals for preventive health services.

“Referral” means the IA CFY program component that involves directing women individuals with abnormal abnormal/alert screening results to appropriate resources for follow-up action.

“Screening mammography” means the use of X-ray of the breasts of asymptomatic women individuals in an attempt to detect abnormal lesions of the breast when they are small, nonpalpable, and confined to the breast.

“Service delivery” means providing, either directly or through contractual arrangements, comprehensive breast and cervical cancer screening and heart cardiovascular disease and stroke risk factor screening, diagnosis, and treatment services through tracking of screening intervals, timeliness of diagnosis, and timeliness of treatment of women individuals.

“Surgeon” means a physician licensed to practice under Iowa Code chapter 148 who treats disease, injury, or deformity by physical operation or manipulation.

“Surveillance” means the IA CFY program component that involves the systematic collection, analysis, and interpretation of health data.

“Susan G. Komen for the Cure” means an international organization with a network of volunteers working through local affiliates and Komen Race for the Cure® events to eradicate breast cancer as a life-threatening disease by advancing research, education, screening, and treatment.

“TBS” or “the Bethesda system” means a system that was developed to provide uniform diagnostic terminology for reporting cervical or vaginal cytologic findings to facilitate communication between the laboratory and the clinician diagnoses, used for reporting Pap test results.

“Triglycerides” means a type of fat that is carried in the blood by very low density lipoproteins. Excess calories, alcohol, or sugar in the body are converted into triglycerides and stored in fat cells throughout the body.

“WISEWOMAN” or “Well-Integrated Screening and Evaluation for Women Across the Nation” means a national program that offers blood pressure, diabetes, and cholesterol risk factor screening, lifestyle intervention, and referral services in an effort to prevent cardiovascular disease.

641—8.2(135) Components of the Iowa care for yourself (IA CFY) program. The IA CFY program shall include the following key components:

8.2(1) Program and fiscal management shall be conducted by ensuring strategic planning, implementation, coordination, integration, and evaluation of all programmatic activities and administrative systems, as well as the development of key communication channels and oversight mechanisms to aid in these processes. Program management shall ensure that infrastructure adequately supports service delivery.

8.2(2) Service delivery of specific and appropriate clinical procedures to detect breast and cervical abnormalities and ~~heart~~ cardiovascular disease or stroke risk factors for ~~women~~ individuals enrolled in the IA CFY program shall be directly provided or provided through contractual arrangements.

a. The IA CFY program shall cover breast and cervical cancer screening and diagnostic services including, but not limited to, the following when those services are provided by a participating health care provider who has a cooperative agreement with the ~~IA CFY program~~ Iowa department of public health. Payment shall be based on Medicare Part B participating-provider rates as released annually at the beginning of each calendar year.

(1) Physical examinations that include two ~~recorded~~ blood pressures pressure measurements in addition to one or more of the following screening services: CBE, pelvic examination, or Pap test;

(2) Height and weight measurements, when provided in conjunction with one or more of the screening services listed in subparagraph 8.2(2) "a"(1) above;

(3) Mammography (screening and diagnostic);

(4) Breast ultrasound, when used as an adjunct to mammography;

(5) Fine-needle aspiration of breast cysts;

(6) Breast biopsies, excisional and nonexcisional (physician charges only; hospital charges are not covered);

(7) Colposcopy of the cervix, with or without biopsy;

(8) Surgical consultations for diagnosis of breast and cervical cancer;

(9) Pathology charges for breast and cervical biopsies;

(10) Anesthesia for ~~breast biopsies~~ program-approved CPT and ICD-10 codes (health care provider charges only; hospital charges and supplies are not covered).

b. Breast and cervical cancer-related services not covered by the IA CFY program include, but are not limited to, the following:

(1) Services not related to breast or cervical cancer screening or diagnosis;

(2) Treatment procedures and services;

(3) Services provided by nonparticipating providers;

(4) Hospital charges for breast biopsies and anesthesia;

(5) Inpatient services.

c. The IA CFY program shall cover cardiovascular disease-related services for ~~those select~~ participants enrolled in the ~~IA CFY program~~ for WISEWOMAN services for whom at least one breast or cervical cancer screening service was paid for using federal funds. Cardiovascular disease-related services shall include, but not be limited to, the following when ~~those services are provided by a~~ participating health care provider ~~who~~ that has a cooperative agreement with the ~~IA CFY program~~ department provides those services. Payment shall be based on Medicare Part B participating-provider rates as released annually at the beginning of each calendar year.

(1) Physical examinations that include two ~~recorded~~ blood pressures pressure measurements;

(2) Height and weight measurements;

(3) Fasting lipid panel that includes total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides; and

(4) Diabetes screening:

1. For a ~~nondiagnosed diabetic~~ an individual who has not been diagnosed with diabetes, fasting blood glucose; and

2. For a ~~diagnosed diabetic~~ an individual who has been diagnosed with diabetes, glycosylated hemoglobin (HbA1c).

d. Cardiovascular disease-related services not covered by the IA CFY program include, but are not limited to, the following:

(1) A follow-up diagnostic visit to a health care provider if one or more screening values are in the CDC-defined abnormal value range;

(2) Repeat laboratory testing;

(3) Any additional testing;

(4) Medication; and

(5) Treatment.

e. IA CFY program cardiovascular intervention shall be conducted as a component of the program for all ~~women~~ individuals who are eligible and enrolled to receive IA CFY program WISEWOMAN services.

f. A health care provider ~~who~~ that has a cooperative agreement with the IA CFY program shall be subject to the following:

(1) The health care provider agrees that reimbursement of procedures and services provided shall not exceed the amount ~~that would be~~ paid under Medicare Part B participating-provider rates as released annually at the beginning of each calendar year.

(2) A mammography health care provider shall ensure that the provider's facility has current FDA certification and ACR or state of Iowa accreditation and is a Medicare and Medicaid-approved facility utilizing BI-RADS and following ACR guidelines for mammography report content.

(3) A board-certified radiologist must be immediately available to determine selection of views and readings when a diagnostic mammogram is performed.

(4) The health care provider shall submit obtained cytology and pathology specimens to a CLIA-certified laboratory for processing. The laboratory shall provide cytological reading and analysis of cervical and vaginal Pap tests by certified/registered cytotechnologists. Cytology (Pap) ~~tests~~ test results shall be reported using current TBS terminology. The laboratory shall provide board-certified pathologists or experienced certified cytotechnologists to rescreen all analyses and readings of cervical and breast biopsies.

(5) The health care provider shall practice according to the current standards of medical care for breast and cervical cancer early detection, diagnosis, and treatment.

(6) Service delivery may be provided in a variety of settings. Service delivery, however, must, ~~however~~, include:

1. Providing screening services for specific geographic areas;
2. Providing a point of contact for scheduling appointments;
3. Providing age and income eligibility screening;
4. Providing breast and cervical cancer screening and ~~heart~~ cardiovascular disease and stroke screening to eligible ~~women~~ individuals;
5. Providing referral and follow-up for ~~women~~ individuals who have alert-value cardiovascular disease screening results;
6. Providing the required reporting system for screening and follow-up activities;
7. Providing population-based education, outreach, and recruitment activities;
8. Providing IA CFY program cardiovascular intervention as a component of the program for all ~~women~~ individuals eligible for and enrolled to receive IA CFY WISEWOMAN program services; and
9. Submitting data within 60 days of service date to establish screening documentation.

(7) The health care provider shall ensure compliance with this chapter and other terms and conditions included in the cooperative agreement.

8.2(3) Referral, tracking, and follow-up utilizing a data system to monitor each enrolled ~~woman's~~ individual's receipt of screening/rescreening, diagnostic, and treatment procedures shall be conducted by the IA CFY program and contracted county board of health designated agency staff.

a. The enrolled ~~woman~~ individual shall be notified by contracted county board of health designated agency staff of the results of the service, whether the results are normal, benign, or abnormal.

b. The data system shall provide tracking of appropriate and timely clinical services following an abnormal test result or diagnosis of cancer.

c. If the enrolled ~~woman~~ individual has an abnormal Pap test or breast screening or an alert-value ~~heart~~ cardiovascular disease risk factor, the health care provider shall provide ~~to the woman individual~~ with a comprehensive referral directing her to appropriate additional diagnostic or treatment services.

d. The comprehensive referral shall be written. Follow-up shall be conducted to determine whether services were timely, completed, or met.

8.2(4) The IA CFY program and contracted county board of health designated agency staff shall provide case management and shall assist participants whose cancer or precancerous breast or cervical condition was diagnosed through the program in obtaining needed treatment services.

8.2(5) IA CFY program staff shall use quality assurance and improvement techniques including use of established standards, systems, policies and procedures to monitor, assess and identify practical methods for improvement of the program and its components.

a. Quality assurance tools shall include utilizing FDA and ACR minimum standards for mammography facilities and CLIA minimum standards for cytopathology and pathology laboratories.

b. Quality assurance measures shall contribute to the identification of corrective actions to be taken to remedy problems found as a result of investigating quality of care.

8.2(6) Professional development shall be provided by the IA CFY program and contracted county board of health designated agency staff through a variety of channels and activities that enable professionals to perform their jobs competently, identify needs and resources, and contribute to ensuring that health care delivery systems provide positive clinical outcomes.

8.2(7) Using a variety of methods and strategies to reach priority populations, the IA CFY program and contracted county board of health designated agency staff shall provide population-based public education and recruitment that involve the systematic design and delivery of clear and consistent messages about breast and cervical cancer and the benefits of early detection. Outreach activities should focus on ~~women~~ individuals who have never or rarely been screened and should work toward the removal of barriers to care (i.e., the need for child care, respite care, interpreter services and transportation) through collaborative activities with other community organizations.

8.2(8) The IA CFY program may develop coalitions and partnerships to bring together groups and individuals that establish a reciprocal agreement for sharing resources and responsibilities to achieve the common goal of reducing breast and cervical cancer mortality and ~~heart~~ cardiovascular disease and stroke mortality.

8.2(9) The IA CFY program shall conduct surveillance utilizing continuous, proactive, timely and systematic collection, analysis, interpretation and dissemination of breast and cervical cancer screening and ~~heart~~ cardiovascular disease and stroke risk factor behaviors and incidence, prevalence, survival, and mortality rates. Epidemiological studies shall be conducted utilizing MDEs and other data sources to establish trends of disease, diagnosis, treatment, and research needs. Program planning, implementation, and evaluation shall be based on the epidemiological evidence.

8.2(10) Evaluation of the program shall be conducted through systematic documentation of the operations and outcomes of the program, compared to a set of explicit or implicit standards or objectives.

641—8.3(135) Participant eligibility criteria. An applicant for the IA CFY program must satisfy the criteria outlined in this rule. If an applicant does not meet these criteria, the applicant shall be provided information by contracted county board of health designated agency staff regarding ~~IowaCare~~ Iowa health and wellness, health insurance marketplace, free care, or sliding-fee clinics available in the area in which the applicant lives.

8.3(1) Age. An applicant for the IA CFY program must satisfy ~~only one of these criteria to participate~~ in the IA CFY program.

a. ~~Women~~ If the applicant is 50 through 64 years of age, the program's priority population, shall the applicant may receive annual breast and cervical (if appropriate) cancer screening.

b. ~~Women~~ If the applicant is 40 through 64 years of age shall, the applicant may receive cardiovascular risk factor screening in addition to breast and cervical cancer screening services.

c. ~~Women~~ If the applicant is 40 through 49 years of age shall, the applicant may receive annual breast and cervical (if appropriate) cancer screening.

d. ~~Women~~ If the applicant is under 40 years of age, if and symptomatic for breast cancer, shall the applicant may receive breast and cervical cancer screening services based upon funding availability.
EXCEPTION: This categorized group is not eligible for cardiovascular services under this program.

e. ~~Women~~ If the applicant is 65 years of age and older shall and the applicant does not have Medicare Part B coverage, the applicant may be eligible to receive annual breast and cervical (if

appropriate) cancer screening ~~if they do not have Medicare Part B coverage~~. EXCEPTION: This categorized group is not eligible for cardiovascular services under this program.

8.3(2) *Income.*

a. IA CFY program income guidelines are based upon 250 percent of the federal poverty level, which is set annually by CMS. New IA CFY program income guidelines will be adjusted following any change in CMS guidelines.

b. Self-declaration of income may be accepted.

c. Eligibility shall be based on net income for the household.

d. Assets shall not affect income status and shall not be counted when eligibility under the IA CFY program is determined.

8.3(3) *Insurance.*

a. The IA CFY program shall determine ~~a woman~~ an individual to be uninsured if the ~~woman~~ individual does not have health insurance coverage.

b. The IA CFY program shall determine ~~a woman~~ an individual to be underinsured if the ~~woman~~ individual has health insurance with unreasonably high copayments, deductibles, or coinsurance or the insurance does not cover IA CFY program-covered services.

c. ~~Women~~ Individuals who have creditable coverage, Medicaid, or Medicare Part B are ~~not~~ eligible if declaring a barrier to services. EXCEPTIONS: IowaCare, Medicaid with spenddown, Iowa family planning network.

8.3(4) *Residency.*

a. ~~A woman~~ An individual must be a resident of Iowa or of a state that shall enroll ~~a woman~~ an individual in the BCCT option of Medicaid if the ~~woman~~ individual is screened or diagnosed by the IA CFY program.

b. ~~A woman~~ An individual who is a resident of a state that does not accept ~~women~~ individuals into the BCCT option of Medicaid and who chooses to continue to receive services in the IA CFY program must be informed that ~~she~~ the individual may not be able to have ~~her~~ the individual's treatment paid for by the BCCT option of Medicaid if ~~she~~ the individual does not receive services in ~~her~~ the individual's state of residence.

c. Proof and length of residency in Iowa are not required. EXCEPTION: An individual is not eligible for cardiovascular services if the individual is not a resident of Iowa.

8.3(5) *Ineligible.* The IA CFY program does not provide coverage for:

a. Men.

~~b. Women with Medicare Part B coverage.~~

~~c. b.~~ Women Individuals 39 years of age and younger unless they have symptoms of breast cancer.

641—8.4(135) Participant application procedures for IA CFY program services.

8.4(1) *Enrollment.* After ~~a woman~~ an individual is determined eligible for services:

a. The ~~woman~~ individual must complete, sign, and return a consent and release form to the IA CFY program. The date on the signed form shall be the participant's enrollment date.

b. Upon enrollment, the participant must select an IA CFY program health care ~~provider and facility.~~

c. The individual is eligible for services for 12 months from the enrollment date, subject to restrictions in program coverage as provided in rule 641—8.5(135).

~~c. d.~~ If a participant is unable to access a particular health care provider due to unavailability of appointments or if a participant requests to change to another health care provider, designated agency staff shall assist the participant in choosing another IA CFY program health care provider who is available ~~in the participant's area.~~

8.4(2) *Reenrollment.*

a. A participant's continued eligibility for program coverage shall be determined annually.

b. No more than 45 days prior to the end of the 12-month coverage period, the IA CFY program shall contact the participant to see if ~~she~~ the participant wishes to reenroll in the program.

c. If a participant wishes to reenroll, ~~she~~ the participant must complete, sign and return a consent and release form before receiving any further services.

8.4(3) Termination of enrollment. The IA CFY program shall terminate a participant's enrollment if the participant:

- a. Requests termination from the program;
- b. No longer meets the criteria set forth in rule 641—8.3(135);
- c. Does not return a signed IA CFY program consent and release form; or
- d. Refuses to receive screening and diagnostic services through an IA CFY program health care provider.

641—8.5(135) Priority for program expenditures.

8.5(1) In the event the IA CFY program director determines ~~that~~ there are inadequate funds to meet ~~participants'~~ program needs, either attributable to a reduction in federal funding from the CDC or to a projected enrollment of ~~women~~ individuals in excess of anticipated enrollment, the program director may restrict new applicants' participation in the IA CFY program as follows:

- a. First priority shall be given to ~~women~~ individuals 50 through 64 years of age.
- b. Second priority shall be given to ~~women 40 through 49~~ individuals under 50 years of age who are symptomatic.
- c. Third priority shall be given to ~~women~~ individuals 40 through 49 years of age who are asymptomatic.
- d. Fourth priority shall be given to ~~women~~ individuals 65 years of age and older who do not have Medicare Part B coverage.

8.5(2) In the event that the financial demand abates, the program director shall withdraw the financial shortfall determination, at which time ~~women~~ individuals shall be eligible for program services in accordance with rule 641—8.3(135).

641—8.6(135) Right to appeal. If an individual disagrees with or is dissatisfied with program eligibility, the covered-service determination, or the decision of the program, the individual has the right to appeal the decision or action.

8.6(1) The appeal shall be in writing and shall be submitted, within ten working days of the decision or action, to the designated agency personnel with whom the individual has been working.

8.6(2) The designated agency staff shall contact a state IA CFY program staff person and shall provide the information regarding the appeal to the staff person.

8.6(3) State IA CFY program staff shall confer with the bureau chief supervising the IA CFY program and provide a decision to the designated agency staff within five business days. A decision made by state IA CFY program staff shall be delivered by telephone, if possible, to the individual making the appeal and shall be followed by a written notification of the decision. The decision of state IA CFY program staff shall be considered a final agency decision in accordance with Iowa Code chapter 17A.

641—8.7(135) Verification for the breast or cervical cancer treatment (BCCT) option of Medicaid. The Iowa department of public health and the Iowa department of human services have coordinated to develop procedures for ~~women~~ individuals to access Medicaid coverage for treatment of breast or cervical cancer or precancerous conditions.

8.7(1) Before referring ~~a woman~~ an individual to ~~her~~ the individual's county of residence's local office of the department of human services, a contracted county board of health designated agency staff member shall document the following regarding the ~~woman~~ individual:

- a. ~~The woman is currently~~ individual was enrolled in the IA CFY program. ~~To be considered enrolled in the program, the woman must meet program age guidelines, have when diagnosed; has had at least one of the basic screening services (Pap test, screening mammogram, or CBE or MRI) or diagnostic procedures paid for by the IA CFY program or with Susan G. Komen for the Cure funds; from family~~

planning centers, community health centers, or nonprofit organizations; and must be in need of treatment for breast or cervical cancer or precancerous conditions; or

b. The ~~woman~~ individual was enrolled in NBCCEDP and has moved to Iowa. To be considered enrolled in NBCCEDP, the ~~woman~~ individual must meet the Iowa program age guidelines; have had at least one of the basic screening services (Pap test, screening mammogram, ~~or~~ CBE or MRI) or a diagnostic procedure paid for by the NBCCEDP or with ~~Susan G. Komen for the Cure~~ funds, from family planning centers, community health centers, or nonprofit organizations; and be in need of treatment for breast or cervical cancer or precancerous conditions; and

c. The ~~woman~~ individual has creditable coverage circumstances or has no creditable coverage for breast or cervical cancer treatment.

8.7(2) The BCCT option of Medicaid is administered by the Iowa department of human services under ~~441 Iowa Administrative Code Chapter 75~~ **441—Chapter 75**, “Conditions of Eligibility.”

These rules are intended to implement Iowa Code sections 135.11(1) and 135.39 and 42 U.S.C. Section 300k, as amended.